FEB 1 6 2010

510(k) Summary
as required by 21 CFR 807.92(c)

Device Name	Parodi Guidewire
Submitters name/contact details	Brivant Ltd, Parkmore West Business Park, Galway, Ireland Contact Details: Tomas Furey Operations Manager, Tel: +353 91 385037 Fax: +353 91 766598
Summary Preparation Date	04th November 2009
Device Name & Classification	Trade Name: Parodi Guidewire Common Name: Guidewire Classification Name: Catheter, Guidewire Device Classification: Class II, 21 CFR §870.1330
Intended Use	The Parodi Guidewire is designed to direct a catheter to the desired anatomical location during diagnostic or interventional procedures.
Device Description	The Parodi Guidewire Assembly is a disposable medical device designed for single use only. It is a multi-component system which can be manipulated to vary the stiffness characteristics as required during a procedure. The device is available in 2 main configurations: • 2-piece system: Comprising a 0.014" guidewire and Outer 0.035" member. • 3-piece system: Comprising a 0.014" guidewire, Outer 0.035" member and an Intermediate stiffener. A 3-piece system is depicted in figure 1 below. The Intermediate Stiffener is not present in a 2-piece system. A hydrophilic coating is applied to the distal portion of the wire of the 0.014" guidewire and the 0.035" outer assembly. PTFE coating is applied to the proximal portions of these devices. The wire is packaged in a polyethylene hoop contained within a sealed pouch. A torque device is included within the pouch to assist with torquing the device if required.

Predicate Devices

Manufacturer	510k	Date
Brivant Ltd, Brivant Guidewire	K060551	07 Jun 2006
Terumo Radiofocus Glidewire for coronary use with platinum coil	K953533	18 Oct 1995
Boston Scientific Amplatz Superstiff Guidewire	K944959	04 Nov 1994

Principle of Operation	The Parodi Guidewire is operated manually by a manual process
Comparison of Technological	Although differing in construction to the predicate wires, the Parodi wire is designed to have similar performance characteristics to the predicate devices

Characteristics	depending on the level of stiffness (configuration) selected by the user. In vitro bench testing was performed to support a determination of substantial equivalence (i.e. tip flexibility, lateral stiffness, tip flexibility and device compatibility) between the Parodi Guidewires (in its various configurations) and the predicate devices. The results of these tests provide reasonable assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use and performs comparably to the predicate devices. The differences in construction and materials between the Parodi wire and the predicate devices raise no new issues of safety and effectiveness such that the Parodi Guidewire is considered substantially equivalent to the predicate devices.
Performance Testing (non-clinical)	In vitro bench testing performance evaluations demonstrated that the Parodi Guidewire met the acceptance criteria defined in the product specification and performed comparably to the predicate. Biological Safety of the device has been established through biocompatibility testing carried out in compliance with ISO 10993-1
Conclusions	Based on safety and performance testing, technological characteristics and the indications for use for the device, the Parodi Guidewire has been demonstrated to be appropriate for its intended use and is considered to be substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

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Brivant, Limited
c/o Mr. Tomas Furey
Operations Manager
Parkmore West Business Park
Galway, Ireland

Re: K093515
Trade/Device Name: Parodi Guidewire System
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter guide wire
Regulatory Class: Class II (two)
Product Code: DQX
Dated: January 18, 2010
Received: January 22, 2010

Dear Mr. Furey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K093515

Device Name: Parodi Guidewire

Indications For Use:
The Parodi Guidewire is designed to direct a catheter to the desired anatomical location during diagnostic or interventional procedures.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K093515